

REMARKS

Claims 17-29 and 32-52 remain pending after amendment. Claims 17-27 are withdrawn from consideration.

Claim Amendment

New claim 52 is added directed to an embodiment wherein the patient being treated is suffering from oxidative damage to the skin. As this is one of the embodiments recited in claim 28 upon which claim 52 depends, no new matter is added by this amendment.

Rejections under 35 USC 101 and 112 (first paragraph)

Claims 28-51 stand rejected under 35 USC 101 and 112 (first paragraph). These rejections are respectfully traversed.

In applicants' prior response, claim 28 was amended to state that the claimed method was directed to the "prophylaxis or treatment of oxidative damage *to the skin*". As a result of the noted amendment, all independent claims are directed to "skin treatment". As all pending claims were so limited, applicants were of the view that the outstanding rejections under 35 USC 101 and 112 (first paragraph) were without basis and should be withdrawn.

However, in the Final Rejection, the Examiner appears to maintain the rejection based on two arguments – i.e., that (1) it is improper for the claims to recite “prophylactic” treatment, and (2) the claims are of such breadth as to embrace the treatment of “aging and wrinkling”, in connection with which the claimed invention is not supported by “either a credible asserted utility or a well established utility”.

These rejections are respectfully traversed.

Initially, applicants inform the Examiner that they present new dependent claim 52 which recites that the claimed method is directed to treatment of a patient suffering from a dysfunction or disease condition arising from oxidative damage to the skin. Claim 52 (as well as remaining claims 36-38) are thus directed to treatment of dysfunction or disease conditions in a patient (as opposed to the “prophylactic” treatment which the Examiner finds objectionable). With regard to this specific aspect of the rejection (whether the claims are improperly directed to prophylactic treatment), claims 36-38 and 52 should be found free of objection and so stated by the Examiner.

As to the rejection of the Examiner on the grounds of non-enablement, the rejection is otherwise respectfully traversed.

The initial burden of establishing a *prima facie* case of non-enablement rests with the Examiner. In re Marzocchi, 169 USPQ 367, 369 (CCPA 1971); In re Strahilevitz, 212 USPQ 561, 563 (CCPA 1982). Indeed, “any assertion by the Patent Office that the enabling disclosure is not commensurate in scope with the protection sought must be

supported by evidence or reasons substantiating the doubts so expressed." In re Dingh-Nguyen and Stenhagan, 181 USPQ 46, 47 (CCPA 1974).

It is only required that the specification describe the invention sufficiently for those of ordinary skill in the art to recognize that applicant invented the subject matter that is now claimed in order to comply with the requirements of the statute. In re Smyth, 178 USPQ 279, 284 (CCPA 1973). The statute merely requires that the scope of the claims bear a reasonable correlation to the scope of enablement provided by the specification to persons of ordinary skill. In re Fisher, 166 USPQ 18, 24 (CCPA 1970). An enabling disclosure is one which allows those skilled in the art to make and use the invention without undue experimentation. In re Wands, 8 USPQ 2d 1400 (Fed. Cir. 1988).

Notwithstanding the Examiner's failure to meet his burden under 35 USC 112, the Examiner takes the position (without factual support) that the claimed invention lacks enabling support in the specification. The Examiner apparently believes that the specification is not enabling for a method for the prophylaxis or treatment of a dysfunction or disease condition of the skin arising from oxidative damage such as might result from irradiation of the skin or other conditions.

Applicants have exemplified a wide variety of dysfunctions or disease conditions arising from oxidative damage at page 20 of the specification. One skilled in the art can readily practice with some predictability the claimed invention, as applicable oxidative

damage conditions are well described. For the Examiner to dismiss applicants' disclosure by stating that certain of such treatments are "incredible" is without factual or legal basis.

The rejections should accordingly be withdrawn.

Request for Interference

As previously requested in applicants' paper dated September 18, 1998, applicants request that an interference be declared between the instant application and U.S. Patent No. 5,679,691 (Ribier et al) which was granted on October 21, 1997.

Again, as previously proposed, applicants propose the following count for the interference:

Count 1: A method for the prophylaxis or treatment of a patient suffering from a dysfunction for disease condition arising from oxidative damage to the skin comprising topically administering to the patient in need thereof an effective oxidative damage-treating amount of a spin trapping compound in a pharmaceutically acceptable carrier for topical administration to said patient.

At least claims 1, 2, 3, 4, 5, 12 and 13 of U.S. Patent No. 5,679,691 correspond to the proposed count.

Claims 28, 29 and 32-52 of the instant application correspond to the proposed count.

Pursuant to 37 CFR 1.607(a)(6), applicants have satisfied the requirements of 35 USC 135(b). Claims 28-51 were originally presented by preliminary amendment dated February 27, 1998, within one year of the October 21, 1997 issue date of U.S. Patent No. 5,679,691. Amended claim 28 in essence corresponds to cancelled claim 31, which claim was presented in the preliminary amendment. The subject matter of amended claim 28 was thus presented within one year of the issue date of U.S. Patent No. 5,679,691.

Applicants also again inform the Examiner that the asserted effective date of the claimed invention corresponding to the count is June 18, 1991, which antedates both the earliest U.S. filing date of December 30, 1994 claimed by U.S. Patent No. 5,679,691, as well as the French priority date of December 30, 1993. Applicants intend to demonstrate priority of invention as to the subject matter of the proposed count.

The instant application claims benefit of priority of the following applications for which support resides for the presently-claimed invention:

- (1) Application No. 08/167,900, filed July 29, 1994;
- (2) Application No. 08/212,800, filed March 15, 1994;
- (3) Application No. 08/52,870, filed April 23, 1993; and
- (4) Application No. 07/716,952, filed June 18, 1991.

Support for the class of compounds defined by the claims resides at pages 8-15 of the specification. Support for the topical application of the active agent to the skin resides at pages 29, 31 and 35, as well as original claim 5. Support for the use of an

ointment or cream topical carrier resides at page 32 as well as original claim 14. Support for the recited dosage amounts resides at page 33. Support for the treatment of radiation or cytotoxic compound exposure resides at pages 7, 20 and 21, as well as original claim 11.

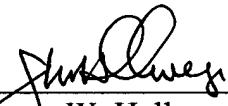
In view of the above, the application is now believed to be in condition for allowance and an early indication of same is earnestly solicited.

In the event that any outstanding matters remain in this application, Applicants request that the Examiner contact James W. Hellwege (Reg. No. 28,808) at (703) 205-8000 to discuss such matters.

Very truly yours,

BIRCH, STEWART, KOLASCH & BIRCH, LLP

By


James W. Hellwege

Reg. No. 28,808

P.O. Box 747

Falls Church, VA 22040-0747

(703) 205-8000